5 November 2004

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

These comments are submitted for addition to FDA Public Docket Number 2004P-0349.

I write as a founding member of the Coalition for Mercury-Free Drugs (CoMeD) and ask that these comments be electronically linked to our FDA Citizen Petition concerning proscribing administration of mercury-containing drugs to pregnant women, infants, children and adolescents.

Thank you for your help in this matter.

Respectfully,

The Rev. Lisa Karen Sykes
Representative of CoMeD

2004P-0349 SUP 1

Coalition for Mercury-free Drugs
(CoMeD)
c/o 3604 Milbrier Pl.
Richmond, VA 23233

5 November 2004

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Citizens Petition 2004P-0349

Dear Sir or Madam:

On 5 November 2000, I collected a sample of urine from my autistic son after giving him DMSA. Doctor's Data International analyzed the sample on 8 November 2000. The results indicated that my then four-year-old son was mercury toxic and had a measured creatinine of 15 mcg/g. The line denoting the level of mercury ran off the righthand side of the page on which the lab report was printed. Over the next fourteen months, after giving him a chelator under the supervision of a physician, I collected urine samples from my son nearly every other week. I was able to document four separate major dumps of mercury in my son's urine during this time.

Aware that the preceding clearly demonstrated my son had suffered mercury poisoning, and that the only significant source of mercury exposure was from Thimerosal, a mercury-based "preservative" containing 49.6% mercury by weight, I began to notify officials of my grave concerns regarding Thimerosal and its likely association to the increasing rate of autism. Prior to my son's diagnosis with heavy metal exposure, I was unaware that Thimerosal was routinely used in pediatric vaccines, eye and ear drops, and even the RhoGam shot, which I had been given at 28 weeks gestation with my son. Even today, most of these same products still carry neurologically significant amounts of mercury and yet continue to be administered and/or sold without any warning to the public of the danger mercury poses to neurological development. *(For the record, let me note I did not consume tuna before, during or after my pregnancy as I find it unpalatable. I also did not eat significant quantities of any fish.)*

Unaware of the Vaccine Adverse Event Reporting System and the National Vaccine Injury Compensation Program, and even the jurisdiction of the Food and Drug Administration, my first correspondence was to the Occupational Safety and Health Administration on 6 December 2000. I closed the letter by stating, "I implore you to examine the extremely detrimental implications of this product (Thimerosal) before more children, genetically at risk, succumb to 237.5 micrograms of ... mercury, an amount that easily exceeds EPA guidelines for 'safe' exposure."

I copied this letter to President Bush by e-mail, and, on 23 April 2001, received a five-page reply from Dr. Kathryn Zoon of the Center for Biologics Evaluation and Research in the Food and Drug Administration. Within the text of this letter, Dr. Zoon wrote:

- "All vaccines licensed in the United Stated by the Food and Drug Administration (FDA) have been demonstrated to be safe and effective ... Under the FDA Modernization Act of 1997, requiring the study of the 'adverse effects on the health of children and other sensitive population from exposure to mercury,' FDA conducted a review of the use of thimerosal in childhood vaccines ... FDA compared exposure levels of infants to ethylmercury from vaccines to existing guidelines for exposure to methylmercury, as there are no existing guidelines for safe exposure to ethylmercury, the metabolite of thimerosal."
- "Determining cause and effect relationships of early toxin exposures to the developing nervous system is very difficult ... Currently, little information is available on the outcome of exposure of the developing human nervous system to the toxic levels of ethylmercury."
- "In addition, available data at present do not provide convincing evidence of an association between autism and exposure to mercury from vaccines."

Absent from this reply was any proof that the level of Thimerosal in the vaccines and other Thimerosal-containing drugs was safe for administration to fetuses and infants, despite the suggestion that all vaccines, even mercury-containing ones, are "safe and effective." Dr. Zoon merely argued that there was not proof of damage, and suggested my son's chelation results documented environmental exposure.

My reply to Dr. Zoon on 29 May 2001 included the following, "Thimerosal in large quantities is an unnecessary component of childhood immunizations, and there are now ample reserves of Thimerosal-free vaccines. Would it not be better to be the first to sound the alarm rather than the last to practice denial? Recall these unsafe vaccines. As one trained in ethics, and specifically in medical ethics, I challenge you to resist institutional inertia, and rapidly study the science that has already been worked out by Dr. Megson, Dr. Wakefield, Dr. McGinnis, Dr. Holmes and Dr. Cave. I find it deplorable that the American public must warn the American government that it is poisoning our children; is your mission statement not to protect the public health?"

On 2 July 2001, Dr. Zoon responded to me a second time, and began, "Reference is also made to your letter of 1 June 2001 to Secretary Tommy Thompson (whom I had copied on this correspondence) requesting an immediate recall of vaccines containing 12.5 mcg or more of ethyl mercury." She continues, "Since there is insufficient scientific data and information to establish that vaccines containing thimerosal within prescribed limits as a preservative present an imminent or substantial hazard to public health or are in violation of FDA laws or regulations, a voluntary or mandatory recall of vaccines or other drugs containing thimerosal is not warranted ... At the suggestion in your letter of May 29, 2001, we contacted Dr. Mary Megson at the Pediatric and Adolescent Ability

Center in Richmond, Virginia ... We also tried to contact the other investigators mentioned in your letter, but were unsuccessful finding telephone numbers or addresses for them."

On 12 July 2001, Kristine Sheedy, Ph.D., of the National Immunization Program also responded to my second letter to Dr. Zoon. Dr. Sheedy explained, "'A mandatory recall requires that the product present an imminent or substantial hazard to the public health.' Current scientific data have not established that products containing Thimerosal, when used within prescribed limits as a preservative, create an imminent or substantial hazard to the public health or are in violation of FDA laws or regulation, and therefore do not justify a recall."

On 8 August 2001, Vice-President Dick Cheney's Special Assistant for Correspondence responded to my correspondence as well and stated:

"The Vice President has asked me to reply to your letter of earlier in the year, telling him of your son's medical history and the potential connections between mercury toxicity and autism. Your comments about the need to recall all Thimerosal-containing vaccines have been carefully noted."

Receiving these correspondences but observing no subsequent action to protect the public from any federal body, including the CDC, the FDA, Secretary of Health and Human Services Tommy Thompson and Vice President Dick Cheney (President Bush did not respond), I turned to the investigative branch of the United States Government.

I wrote my first letter to a federal oversight agency on 15 January 2004. I addressed this letter to Martin A. Campbell, Acting Deputy Inspector General, Office of Investigations, for Health and Human Services. In that letter I stated:

In addition to expressing my concerns over Thimerosal, I now questioned the conduct of officials in our national health agencies and executives of the pharmaceutical industry after learning of the Simpsonwood Transcripts, which offer evidence of collusion between these parties. In my complaint, I stated, "I ask you to protect those not yet injured and defend those who already are. Let us endeavor together to make pharmaceutical companies accountable, and to investigate thoroughly the meeting which took place at Simpsonwood June 7-8, 2000 in Norcross, Georgia ... The remarks made at this meeting, where the finding of the Vaccine Safety Datalink analysis of Thimerosal containing vaccines and neurodevelopmental outcomes were reviewed by a panel of experts in private by the government and industry, are in direct contradiction to statements made by these same individuals before the Institute of Medicine and other public forums ... Surely, this nation does not make privileged the knowledge necessary to protect one's newborn from harm, yet with great sorrow, I must observe that it seems the CDC and the FDA do."

On 11 March 2004, Matt Kochanski, Director of the Investigative Branch of the Office of Investigations, Health and Human Services responded, "Normally, we would refer your information to the CDER, however, our research into the current status of thimerosal use in vaccines render this course of action moot...Currently, all vaccines in

the recommended childhood immunization schedule that are for us in the U.S. market contain no thimerosal or only trace amounts. (Those with a concentration of less than 0.0002% contain what is considered 'trace,' or insignificant, amounts.)"

Upon receiving this correspondence, which failed to even acknowledge the Simpsonwood Meeting, which provided clear misinformation, and which was written with great condescension, I became so angry that I began the "Office of Special Counsel Project." This project initially involved 15 families from across the nation, each with convincing evidence of their autistic child's mercury toxicity. Together with fellow parent and advocate Kelli Ann Davis, who served as the project manager for this endeavor, I crafted a letter detailing nine serious allegations against the CDC, the FDA, and the IOM. Laura Bono and Lori McIlwain, both parent-advocates, together with Kelli Ann Davis and myself, edited the letter.

This letter was sent to the Office of Special Counsel, and posted across the Internet, for other concerned parents and individuals to download, sign and mail also. In the end, the Office of Special Counsel received hundreds of copies of the following letter, each signed by a person convinced that the conflict-of-interest in our national health agencies had endangered and damaged a child they loved through the widespread and unsound use of mercury in approved vaccines and other drugs.

The letter, in full, reads as follows:

April 2004

Scott Bloch, Special Counsel
U.S. Office of Special Counsel
1730 M Street, N.W. Suite 300
Washington, D.C. 20036-4505
(202) 254-3600 (202) 653-5151 Fax

Honorable Special Counsel Bloch,

We, the undersigned parents, have united to advocate for the reform of the national vaccine program/industry that has unnecessarily exposed our children to unsafe levels of mercury. Mercury, a known neurotoxin, which comprises 49.6% of the antiquated preservative Thimerosal, is used in many pediatric immunizations, flu shots, and Rho-D injections such as RhoGAM. We have clinical data proving that our children have suffered mercury-induced neurological disorders due to Thimerosal, and, in realizing that more children succumb daily to this preventable fate, we have resolved to bring this scandal to national prominence. Seeking to enlist your oversight and resources in investigating this serious issue, we make the following charges:

1). The Centers for Disease Control (CDC) is characterized by egregious conflicts of interest, which have compromised the safety of the vaccine supply, while putting our nation's children at risk. Placing pharmaceutical profits and patronage above our children's health, the CDC has failed to evaluate objectively the cumulative mercury exposure incurred through the standard infant immunization schedule from 1980 to present. Furthermore, officials have refused to recall products containing this potent neurotoxin, despite the objections of clinical researchers and parents.

2). The CDC, Food and Drug Administration (FDA), and pharmaceutical companies colluded at the Simpsonwood Retreat Center in Norcross, Georgia on June 7 and 8, 2000. At this closed meeting, a CDC study authored by Dr. Thomas Verstraeten was discussed. The scientists, CDC, FDA and pharmaceutical officials acknowledged the statistical correlation between mercury exposure through pediatric vaccines and neurological disorders in children including autism, ADHD, stuttering, tics and speech and language delays. This version of the Verstraeten study was never released to the public and could only be accessed through the Freedom of Information Act (FOIA). Evidence of their collusion is recorded in the Simpsonwood Transcripts, also accessed through FOIA. Both documents can be reviewed at http://www.nationalautismassociation.org/library.php and/or http://www.NoMercury.org/is_mercury_dangerous.htm

3). Dr. Verstraeten later denied a link before an Institute of Medicine (IOM) Committee Panel on July 16, 2001, and released a different version of the same study showing no correlation between Thimerosal and neurological disorders in the November 2003 *Pediatrics* Journal. The Simpsonwood Transcripts call the veracity of the latter Verstraeten Study into question. Nonetheless, the Members of the IOM, at their February 9, 2004 meeting, included this Verstraeten Study in the presentation schedule without ever raising the question of its integrity. At the close of the meeting, when questioned, IOM Chair Marie McCormick acknowledged that each member of the IOM Committee received a copy of the Simpsonwood Transcripts.

4.) According to official communication from the CDC, various datasets compiled for the Verstraeten Study showing a relationship between Thimerosal and neurological disorders no longer exist. We fear further destruction of data, and therefore ask that steps be put in place IMMEDIATELY to safeguard the Vaccine Safety Datalink (VSD) Database and other pertinent CDC information regarding this important issue.

5). Federal and medical authorities including Health and Human Services – Office of Investigations (HHS-OI) and the American Academy of Pediatrics (AAP) incorrectly state that Thimerosal/mercury is out of the vaccine supply. *It is not.* Vaccines containing 25 mcg of mercury continue to be produced with documented expiration dates at the end of 2005. These vaccines pose an immediate and significant danger to America's children. *Thimerosal-containing vaccines and products must be recalled immediately, and Thimerosal must be banned.*

6). Independent researchers have been arbitrarily restricted from the Vaccine Safety Datalink (VSD) after previously being given access. This *taxpayer-funded* database, which contains vaccine, vaccine-dose, and health histories of millions of children and is compiled

from multiple Health Management Organization (HMO) databases across the United States, must be open to all researchers regardless of CDC or government affiliation. We accuse the Internal Review Board (IRB) of denying access to the VSD—under the false pretext of privacy issues—to independent researchers Dr. Mark Geier and Mr. David Geier, who have published over 50 peer-reviewed articles. Additionally, we believe this action may have violated the Data Quality Act and Data Access Act requiring further investigation from you to determine compliance. Such subterfuge, perpetuated by the CDC, does nothing to alleviate our mistrust in an organization that continues to protect the industry they are appointed to regulate.

7). The methodology of government-sponsored studies of Thimerosal and its connection to neurological disorders in children has been exclusively statistical and epidemiological in nature. Such studies cannot assess the genetic vulnerability of subpopulations. Additionally, the ever-expanding clinical evidence amassed by clinical researchers is being ignored. We call upon the government to fund open and impartial clinical studies. While officials at the CDC and FDA continue to hide behind statistics, we parents will continue to offer our children's clinical documentation as evidence that mercury, in any amount, is not, and never will be, safe for injection into newborns and pregnant women.

8). Claims for Thimerosal-induced vaccine injuries from government-mandated vaccines are being hampered and delayed in the National Vaccine Injury Compensation Program (NVICP). Additionally, the statute of limitations for pursuing compensation for mercury-induced neurological disorders excludes most families from gaining legal restitution from the American Government.

9.) Injecting mercury (Thimerosal) in excess of Environmental Protection Agency (EPA) standards without prior informed consent, represents a significant and widespread violation of civil rights.

We are convinced there is not a more pressing issue, nationally or internationally, than the epidemic of autism and the devastated lives left in its ruins. The cost of this negligence will be measured economically, intellectually, and politically for years to come.

It is tragically ironic that in an era when the American Government is concerned about biological and chemical warfare, our own vaccine supply has been poisoned with a lethal neurotoxin while being administered by the same federal agencies charged with its oversight.

We look forward to the results of your investigative findings. Without immediate action from the federal government, confidence in the national immunization program will continue to erode."

On May 20, 2004, Special Counsel Scott Bloch issued the following press release and letter to Congress:

OSC Forwards Public Health Concerns on Vaccines to Congress

For Immediate Release: 5/20/04
Contact: Cathy Deeds 202-254-3600

The Office of Special Counsel (OSC) today forwarded to Congress hundreds of disclosures alleging public health and safety concerns about childhood vaccines that include a mercury-based preservative known as thimerosal, and its possible link to neurological disorders, including autism. Notwithstanding a new Institute of Medicine study released yesterday that concludes there is no link between thimerosal and autism, the OSC sent copies of the letters to both Senator Judd Gregg and Rep. Joe Barton, to ensure that the proper Congressional oversight committees are aware of these serious allegations.

While Special Counsel Scott J. Bloch shares many of the concerns about the allegations, many of them from parents of children with autism or other neurological disorders, the OSC does not have jurisdiction over disclosures from private citizens. In the event, however, that a federal employee comes forward with information on this issue, OSC would then have jurisdiction to determine whether there is a substantial likelihood that the information discloses a violation of any law, rule or regulation ... or a substantial and specific danger to public health and safety.
5 U.S.C. §1213(b)

"It appears the science is inconclusive, not definitive," Special Counsel Bloch said. "Based on my limited review of the literature, there appears to be equally qualified experts on both sides of the emotional scientific and medical debate. This strikes me as a far-reaching public health issue that warrants further study and awareness, particularly because it affects the most vulnerable among us."

Special Counsel Bloch continued, "I think it is important that government agencies be as certain as possible that these vaccines containing mercury, a known potent neurotoxin, have undergone sufficient, reliable scientific review definitively answering the legitimate medical questions, such as, whether there is any medically necessary reason for including mercury in vaccines given to children. Furthermore, parents and others should also know that they can request a mercury-free vaccine."

A copy of the Special Counsel's letter to Congress follows.

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OSC is an independent investigative and prosecutorial agency and operates as a secure channel for disclosures of whistleblower complaints and abuse of authority. Its primary mission is to safeguard the merit system in federal employment by protecting federal employees and applicants from prohibited personnel practices, especially retaliation for whistleblowing. OSC also has jurisdiction over the Hatch Act and the Uniformed Services Employment and Reemployment Rights Act. For more information please visit our web site at www.osc.gov or call 1-800-872-9855.

Special Counsel Scott Bloch's letter to Congress

May 20, 2004

The Honorable Judd Gregg
United States Senate
Chairman, Committee on Health,
Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510-6300

The Honorable Joe Barton
U.S. House of Representatives
Chairman, Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Re: OSC File Nos.: DI-04-1399, et al.

Gentlemen:

The U.S. Office of Special Counsel (OSC) is authorized to receive disclosures of information from federal employees, former federal employees or applicants for federal employment alleging violations of law, rule, or regulation, gross mismanagement, gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. 5 U.S.C. § 1213(a) and (b). As Special Counsel, if I find, on the basis of the information disclosed, that there is a substantial likelihood that one of these conditions exists, I am required to advise the appropriate agency head of my findings, and the agency head is required to conduct an investigation of the allegations and prepare a report. 5 U.S.C. § 1213(c) and (g).

I have recently received hundreds of disclosures from private citizens alleging a widespread danger to the public health, specifically to infants and toddlers, caused by childhood vaccines which include thimerosal, a mercury-containing preservative. As you know, the vaccine program is administered by the U.S. Department of Health and Human Services (HHS), over which you have oversight jurisdiction. Because none of the individuals making the disclosures are federal employees, former federal employees or applicants for federal employment, OSC lacks jurisdiction over these cases and can legally take no action on the allegations. 5 U.S.C. § 1213(a)(1). I hasten to add, however, that based on the publicly available information, as discussed briefly below, it appears there may be sufficient evidence to find a substantial likelihood of a substantial and specific danger to public health caused by the use of thimerosal/mercury in vaccines because of its inherent toxicity.

Due to the gravity of the allegations, I am forwarding a copy of the information disclosed to you in your capacity as Chairmen of the Senate Committee and House Committee with oversight authority for HHS. I hope that you will review these important issues and press HHS for a response to this very serious public health danger.

The disclosures allege that thimerosal/mercury is still present in childhood vaccines, contrary to statements made by HHS agencies, HHS Office of Investigations and the American Academy of Pediatrics. According to the information provided, vaccines containing 25 mcg of

mercury and carrying expiration dates of 2005, continue to be produced and administered. In addition, the disclosures allege, among other things, that some datasets showing a relationship between thimerosal/mercury and neurological disorders no longer exist, that independent researchers have been arbitrarily denied access to Centers for Disease Control and Prevention (CDC) databases, and that government-sponsored studies have not assessed the genetic vulnerabilities of subpopulations. Due to their heightened concern that additional datasets may be destroyed, these citizens urge the immediate safeguarding of the Vaccine Safety Datalink database, and other relevant CDC information, so that critical data are not lost.

The disclosures also allege that the CDC and the Food and Drug Administration colluded with pharmaceutical companies at a conference in Norcross, Georgia, in June 2000, to prevent the release of a study which showed a statistical correlation between thimerosal/mercury exposure through pediatric vaccines and neurological disorders, including autism, Attention-Deficit/Hyperactivity Disorder, stuttering, tics and speech and language delays. Instead of releasing the data presented at the conference, the author of the study, Dr. Thomas Verstraeten, later published a different version of the study in the November 2003 issue of Pediatrics, which did not show a statistical correlation. No explanation has been provided for this discrepancy. Finally, the disclosures allege that there is an increasing body of clinical evidence on the connection of thimerosal/mercury exposure to neurological disorders which is being ignored by government public health agencies.

I recognize that Congressman Dan Burton, Chairman of the House Committee on Government Reform, held hearings on CDC Activities Related to Autism most recently in April 2002 as well as from 1999-2001. During those hearings Dr. David Baskin, a Baylor School of Medicine neurologist, testified about his research and the serious consequences of exposure to mercury. Dr. Baskin concluded that even if the link to autism has not yet been conclusively proven, based on what is known to date about mercury as a deadly neurotoxin and because thimerosal is not an essential component to the vaccine, there is no reason to continue to purposefully inject it into the bloodstream of infants.

I believe these allegations raise serious continuing concerns about the administration of the nation's vaccine program and the government's possibly inadequate response to the growing body of scientific research on the public health danger of mercury in vaccines. The allegations also present troubling information regarding children's cumulative exposure to mercury and the connection of that exposure to the increase in neurological disorders such as autism and autism-related conditions among children in the U.S. Indeed, the considerable scientific debate that continues to surround the issue of autism and vaccines in the U.S. is exemplified by the recent publication of an article in the National Journal, "Upping the Autism Ante," describing some research which seems to show an association between exposure to thimerosal and autism, and a report released just yesterday by the Institute of Medicine that found no link between vaccines and autism. I have attached a copy of the National Journal article for your review.

Accordingly, because OSC lacks jurisdiction, we are closing our files on these cases. I am also available for any questions you may have, or to offer the services of this office to assist you with any inquiry.

Sincerely,

Scott J. Bloch

Enclosures

Unlike the previous governmental officials, Special Counsel Bloch was forthcoming in his public statement and acknowledged the danger mercury presents to the public health. His concern for the well-being of this nation's citizens is exceptional, both in its integrity and its rarity, and a stark contrast to the widespread dissembling practiced by the other federal officials with whom I have corresponded.

In addition to the Office of Special Counsel, the President's Council on Integrity & Efficiency (PCIE) responded to the OSC Project letter, which was copied to all of Congress and many federal agencies involved in the areas of either federal investigations or national science policy, and, on 22 April 2004 stated, "Your complaint will be present to the IC (Integrity Committee) at its next meeting for review and further action, as appropriate."

On 21 July 2004, PCIE followed-up with its determination: "The IC decided to refer your complaint to Ms. Dara Corrigan, Acting IG, HHS, for review and further action, as appropriate."

In a letter dated 19 July 2004, Michael E. Little, Deputy Inspector General for Investigations, Office of the Inspector General, Office of Investigations for Health and Human Services wrote, "Upon review of the correspondence you provided to the PCIE, in conjunction with further research into the matter, we have determined that your above allegation (using mercury "in order to increase the manufacturer's profit margins") represents a potential conflict-of-interest issue which may be criminal in nature and therefore falls within the Department of Health and Human Services (HHS), Office of the Inspector General (OIG), Office of Investigations' (OI) authority to investigate."

Letters from Homeland Security, Clark Kent Ervin dated 15 April 2004, the Environmental Protection Agency, Kimberley E. Bynum, dated 16 April 2004, and the Office of Government Ethics, Ed Pratt, dated 22 April 2004 all specify this issue as outside (their) "jurisdiction" or "statutory oversight authority."

On 4 August 2004, a small group of scientists and parent-advocates, including myself, called the Coalition for Mercury-free Drugs (CoMeD) filed FDA Citizen Petition 2004P-0349, to which this comment is now being submitted. This petition seeks to make the FDA enforce its own *Code of Regulations at Section 610.15(a)* requiring drugs and all their components to be proven safe ("not be toxic to the recipient") by *appropriate* chronic toxicity studies. In addition, the National Vaccine Injury Compensation Act places upon the Secretary of Health and Human Services the responsibility for minimizing potential adverse reactions from vaccines by making them as safe as possible. The presence of mercury in our vaccines and other drugs is in violation of these specifications.

Having waited for two and a half months since HHS-OIG opened an investigation into the use of mercury in drugs to increase the manufacturer's profit margin, without further communication from the Office of the Inspector General for Health and Human Services, CoMeD authored the letter that follows and mailed it to 105 recipients:

5 October 2004

Ms. Dara Corrigan
Acting Inspector General
Health and Human Services
330 Independence Avenue, SW
Room 5250
Washington, DC 20201

Dear Acting Inspector General and Deputy Director Corrigan:

While we appreciate your stated "commitment to ensuring the integrity and effectiveness of all the programs of HHS" (July 19 letter of response from Mr. Michael Little, Deputy Inspector General for Investigations to Rev. Lisa Sykes, Representative of CoMeD), our urgent concern is **not** for the programs of your agency. **Our urgent concern is, *as it should be*, for the children of this nation, who are daily at risk, from mercury.**

They continue to suffer excessive and unwarranted mercury exposure, and subsequent neurological damage and neurodevelopmental disorders, due to mercury-containing drugs. At *epidemic levels*, this damage ranges from the mild conditions such as ADD and ADHD (for which the pharmaceutical industry cheerfully peddles its ineffective antidepressants) to the severe disorder known as autism, a misnomer for mercury poisoning. This epidemic, manufactured by the pharmaceutical companies and sanctioned by our nation's health agencies, has reached catastrophic levels. Currently, even the Centers for Disease Control and Prevention (CDC) admit at least one child in six (or about 680,000 annually based on the CDC's 2003 data) is diagnosed with a neurodevelopmental disorder. **This 1-in-6 plague upon our children and our society includes the 1-in-166 children (or about 25,000 kids annually) who are diagnosed as having an autism spectrum disorder.** We must now recognize that we have created the most neurologically-damaged generation of children to ever live.

As any who understand the highly toxic and insidious nature of mercury know, this damage has occurred, in large part, because the FDA knowingly approves drugs containing excessive levels of mercury in the 'preservative' Thimerosal. The toxicity of Thimerosal compromises neurological development, from gestation *through early adulthood*, when, *in spurts*, the brain's higher-level cognitive pathways are developing. *To this day*, Thimerosal, *at the levels now being routinely administered in vaccines and other drugs, has not been proven safe in the requisite scientifically sound and appropriate primate chronic toxicology studies suitable for any known highly toxic poison*. Under the FDA's general approach to safety, those studies should have been conducted, *and established safety for Thimerosal or mercury content* at a level 100 times higher than the maximum level permitted in the

drug formulation. Even today, the FDA, HHS, CDC, IOM and the pharmaceutical industry still conspire to misrepresent the inherent risk of mercury poisoning, through mercury-containing drugs, to the public. **These agencies trivialize the risk by using terms like "mercury-free," "Thimerosal-free," "preservative-free," a "small amount," and "trace" to describe the mercury or Thimerosal content of drugs that still contain toxicologically significant levels of any poisonous compound of mercury.**

Moreover, *under the guise of protecting the public health*, the Federal Government has established vaccination recommendations that put children at risk of excessive mercury exposure when the States impose them upon the public. *Without the opportunity of truly informed consent*, parents are made unwitting accomplices in the toxic injury of their own children and in the violation of **their children's Constitutional Right to Bodily Integrity**.

On July 19, 2004, Mr. Michael Little, Deputy Inspector General for Investigations reviewed our nine allegations against the CDC. *Responding to concerns from Mr. Kenneth M. Donohue, of the President's Council on Integrity and Efficiency*, Deputy Inspector Little, stated, "***we have determined that your above allegation (using mercury to increase profit margins) represents a potential conflict-of-interest issue which may be criminal in nature and therefore falls within the Department of Health and Human Services, Office of the Inspector General, Office of Investigations' authority to investigate.***"

While your office investigates the gross conflict-of-interest that has permitted hundreds of thousands of American citizens to be poisoned in infancy, the resulting threat to the unborn and newborn continues unchecked. You need only review the mercury content of the majority of available doses of Influenza Type B Vaccine. *Ignoring the proven neurotoxicity of Thimerosal and ethyl mercury at levels well below those in this mostly Thimerosal-preserved vaccine,* a vaccinate-at-any-cost government policy negligently recommends vaccinating American children over 6 months of age and pregnant women. Given the preceding, even you should realize your investigation has not stopped the real and on-going damage and risk of damage to innocent life from mercury poisoning that such Thimerosal-containing vaccines present.

Seeking to stop a clear and present danger to that nation's children, the Coalition for Mercury-Free Drugs (CoMeD), on August 4, 2004, filed a Citizen Petition with the FDA, urgently requesting that this agency:

- Immediately issue an order barring the administration of any disease-preventive Thimerosal-containing vaccine, or other such mercury-containing pharmaceutical product, that contains more than "trace" (more than 0.5 micrograms per dose) levels of Thimerosal to pregnant women and children under the age of 36 months.

- Suspend the approval or licensing of any FDA-regulated product that contains Thimerosal or any other mercury-based compounds as a preservative, or adjuvant, in the final formulation unless the total level of said compounds is *not more than* 0.5 micrograms of mercury per dose for vaccines and similar biological products or, *for other pharmaceutical products administered more frequently*, not more than 0.5 micrograms of mercury per day.

- Announce a recall of all batches of multi-dose vaccines that contain a Thimerosal preservative level of more than 0.001 %.
- Issue orders:
  - Banning vaccines, and other drugs, containing more than 0.5 microgram (μg) of mercury per dose of product from being introduced into commerce in the United States and any of its territories, possessions, and commonwealths after 1 January 2006.
  - Requiring, *after 1 January 2006*, the recall and destruction of ALL:
    - vaccines remaining in commerce that contain more than 0.5 μg of mercury per dose and
    - other drug products remaining in commerce that contain more than 1.0 μg of mercury per mL (or g) of drug,

    unless the manufacturer thereof can prove that the mercury-based compound in said vaccine or other drug product causes no adverse neurological health outcomes in any group or subgroup of *susceptible* individuals, including, but not limited to, males, fetuses, newborns, children, and adolescents.

Surely, the scope of this criminal conspiracy and collusion between government and the pharmaceutical industry is reflected in the failure of even one single government agency to act decisively in stopping the damage to human life and our nation's well-being. **With each passing day**, *while you investigate this conflict-of-interest*, **thousands of additional children are losing some portion, or, *in the worst cases*, all of their "functional lives."** At this point, we must and do hold you, and your oversight branch, HHS, responsible for your knowing failure to protect the public from an identified, real, and on-going threat to our nation.

We assert that you and others in our government know the gravity of this situation. We would reference Mr. Raynard S. Kington, NIH's Deputy Director and Ethics Chief, when he commented on conflict-of-interest within NIH to the press: "***We've learned there are vulnerabilities in our system of oversight...that give us pause.***" [**See**, for example, "NIH Bans Collaboration With Outside Companies; Policy Comes After Conflict-of-Interest Inquiry" by Rick Weiss, Washington Post Staff Writer, September 24, 2004; Page A23.]

Surely, amidst the unstated concerns that trouble Mr. Kington, must be:

- The **reckless use of** the poison **Thimerosal**, *that, in the human body, releases ethyl mercury, a known acute neurotoxin*, **in drugs at levels that have <u>not</u> been proven to be safe, and**
- A **blatant cover-up**, by the HHS, NIH, CDC, and the FDA, **of that failure to prove safety for each mercury-containing drug product** <u>before</u> that product was accepted, approved, or licensed for use.

Moreover, the cover-up within your Department, as it seeks to hide its pervasive failure to protect the health of the public, and its on-going and knowingly collusive actions with the pharmaceutical industry, are still causing fetuses and infants to be maimed for life.

In the two and a half months since you received an official letter (from the concerned parents and researchers who went on to found **CoMoD**) in which those responsible individuals clearly identified gross conflicts-of-interest within the CDC, FDA, HHS and IOM, how many lives have been lost? How many more have been moderately to severely diminished? How many families have been devastated? How many more children will one day require institutionalization? *Why is there no rapid-response team to come to the aid of our children and issue immediate warnings to the general public, until a recall can be undertaken?* **Why has no one stated that, *given the lack of proven safety for the mercury levels present*, our nation's supply of "flu" vaccine is unsafe?**

Why has HHS or the CDC, knowing the preceding reality, failed to warn individuals, and especially pregnant women and children, that the "flu" vaccine represents an unwarranted and ill-advised mercury-exposure risk? Why, at a minimum, has the CDC not required all of the "reduced-Thimerosal" be reserved for use in children less than three years of age?

Though Mr. Little closes his letter of July 19 with these words: "*....we....hope this adequately responds to your concerns*," we can assure you nothing, short of urgent measures and major governmental reforms, will ever adequately address our concerns. **You see, our lives are devoted to children who will likely never read, never speak, and never know the consolations of human communication, because the mercury your agency sanctioned, and our states required, as part of a childhood immunization schedule, has irreversibly damaged their brains.**

We suggest you treat the insidious presence of mercury, at neurotoxic levels and mislabeled as a preservative named "Thimerosal" in our drug supply, as an instance of domestic terrorism, and respond appropriately. To fail in warning the American public of this clear and present danger is to fail in your responsibility as an Inspector General. Anyone who does not act boldly to protect our nation's children is not worthy of their office nor of the trust we have place(d) in them.

We formally request a meeting to discuss the progress of your investigation to date and the immediate need to protect the citizens of our nation from a clear and present danger.

Respectfully,

Rev. Lisa Karen Sykes
Representative of **CoMoD**

On Behalf Of Herself And:

Dr. Brian S. Hooker
Representative of **CoMoD**

Dr. Paul G. King
Representative of **CoMeD**

Ms. Leslie Weed
Representative of **CoMeD**

Ms. Kelli Ann Davis
Representative of **CoMeD**

At the time of this comment's submission to the FDA Docket, 5 November 2004, almost four years since I began my letter writing campaign to have Thimerosal recalled, **no action** has yet been taken, and **no public warning** has yet been issued, by any federal agency or official, to protect the nation's fetuses and children from unnecessary and preventable damage due to mercury-exposure through FDA approved pharmaceuticals which contain unsafe levels of this neurotoxin. This year's flu shot is a perfect illustration of the CDC's continuing penchant for injecting vulnerable individuals and populations with a known neurotoxin in amounts that have not been proven safe. I recoil from adding up the number of children we have unnecessarily lost to mercury toxicity in these past four years.

When did it become the responsibility of the American public to prove a known neurotoxin dangerous for administration, particularly to our fetuses and infants, rather than the duty of the government to prove it safe before licensing and distribution?

Dumbfounded, I wait in anticipation for the time America's government will break its silence, and at last, come to the protection of her children. The only one disabled more than our mercury-toxic children, by this gross and historic negligence, is America herself.

Respectfully submitted,

The Rev. Lisa Karen Sykes
Representative of CoMeD